

**LIST OF TEST PRODUCTS, COMPARATOR PRODUCTS AND EFFECTIVE SUBMISSION DATE FOR BIOEQUIVALENCE  
STUDY REPORT FOR YEAR 2001 - 2002**

**3RD LIST**

*Bil.(50)d/m.BPFK/007/3.8 (08/05/2001)*

Bil.	TEST PRODUCTS (Pharmaceutical name)	Comparator Products		Effective Date for Submission of BE Study Report	Closing Date for Submission of BE Study Report of Registered Products	
		Trade Mark/Registration No.	Manufacturer	New Application	Imported Products	Local Products
1.	Theopylline	i) Nuelin Tablet 125mg (MAL19872131A)	Inova Pharmaceuticals (Australia) Pty Ltd, Australia	01/07/2001	31/12/2001	30/06/2002
		ii) Neulin Tablet 200mg (MAL19872136A)	* formerly known as 3M Pharmaceuticals (Australia) Pty Ltd, Australia			
		As agreed upon in "Mesyuarat Jawatankuasa Kajian Bioekuivalens Kebangsaan 2/2015, 7 September 2015, the following product is being added to the existing list of comparator:-				
		i) Pharmaniaga Theophylline Tablet 125mg (MAL19872133AZ)	Pharmaniaga Manufacturing Berhad			
2.	Propranolol	i) Inderal Tablet 10mg (MAL19870030ARZ)	Astrazeneca UK Limited, United Kingdom	01/07/2001	31/12/2001	30/06/2002
		ii) Inderal Tablet 40mg (MAL19870042ARZ)	Astrazeneca UK Limited, United Kingdom			

3.	<b>Cimetidine</b>	i) Tagamet Tablet 200mg (MAL19950282A)	Sigma Pharm Pvt Ltd, Australia	01/07/2001	31/12/2001	30/06/2002
		As agreed upon in “Mesyuarat Jawatankuasa Kajian Bioekuivalens Kebangsaan 1/2016, 16 June 2016, the following products are being added to the existing list of comparator:-				
		i) Apo-Cimetidine Tablet 200mg (MAL19984721ARZ)	Apotex Inc., Canada			
		ii) Apo-Cimetidine Tablet 400mg (MAL19984723ARZ)	Apotex Inc., Canada			
4.	<b>Carbamazepine</b>	i) Tegretol 200mg Tablet (MAL20000032ARZ)	Novartis Farma S.p.A., Italy	01/07/2001	31/12/2001	30/06/2002

Updated on 28/03/2017